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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,315	09/08/2000	Kathleen E. Rodgers	98.009-B1	3507

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/658,315	RODGERS ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 2-10-03 is acknowledge. Claims 1-2, 31-33, 35-42 were canceled. Claims 43 was amended and claims 53-59 was added. Claims 43-59 are pending in this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 43-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,239,109. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The US Patent teach a method for augmenting erythropoiesis comprising erythropoid progenitor cells with a peptide corresponding to SEQ. ID. NO4. The sequence corresponding to SEQ. ID. NO 4 of the reference is identical to the peptide corresponding to SEQ. ID. NO. 4 of the instant application (see claim 1 of the US Patent and claim 2 of the instant application). Both, the Patent and the instant application, teach a similar dosage range and concentration range for the active agent (see claim 3-10 of the Patent and the claims 40-43 of the instant application). Thus the

US Patent and the instant application sufficiently overlap it the subject matter and thus are not patentably distinct from each other.

3. Claims 43, 48 , 50, 51, 53-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 22 of U.S. Patent No. 6762167. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The US patent claims a method for chemotherapy in a human patient, wherein the improvement comprises administering to the human chemotherapy patient an amount of at least one active agent effective to treat chemotherapy side effects, or to reduce the frequency, severity, or the frequency and severity of chemotherapy side effects comprising administering the peptide of the sequence Asp-Arg-Val-Tyr-Ile-His-Pro-Phe (see claim 1). The sequence claimed in the US patent corresponds to SEQ ID 32 in instant application. The US patent claims that the chemotherapy side effects include anemia (see claim 1 and claim 22). Note that instant claims recite that augmentation of eryhtropoiesis is used to treat anemia as s result of chemotherapy, cancer and radiotherapy (see claim 43 of the instant application. Thus, practicing the claimed method of claimed US Patent would necessarily achieve augmentation of eryhtropoiesis because the same peptide, corresponding to SEQ ID NO. 32, is administered to treat the same condition, anemia associated with chemotherapy and cancer. Thus, the subject matter claimed in the US patent and the instant application are not patentably distinct from each other.

4. Claims 43-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,335,195 in view of Wong et

al. (US 6083747) and Iwata et al (US5824297). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The US Patent teach a method for accelerating the proliferation of hematopoietic pluripotent progenitor cells comprising contacting the cells with an amount effective to accelerate proliferation of the cells of at least one active agent comprising a sequence of at least seven contiguous amino acids of groups R.sup.1 -R.sup.8 in the sequence of general formula I (see claim 1). The US patent specifically claims wherein the active agent is selected from the group consisting of, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21,SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:28, SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO: 32, SEQ ID NO:33, SEQ ID NO: 34; SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, and SEQ ID NO:38 (see claim 3). Note that these are the same sequences claimed in the instant application. The difference between the US patent and the instant claims is that the US patent does not specifically disclose the augumentation of erythroid progenitor cells.

However, All circulating blood cells develop from pluripotent stem cells through the process of hematopoiesis. Hematopoietic stem cells are undifferentiated cells capable of self-renewal and differentiation into committed progenitor cells of the myeloid, erythroid, megakaryocytic and lymphoid blood cell lineages (see col. 1, lines 21-30 in Wong et al. and col. 5, lines 54-58 of Iwata et al.). Thus, a method of accelerating the proliferation of hematopoietic pluripotent progenitor cells would result in the augmentation of the erythroid cells because pluripotent cells differentiation into cells from the erythroid. Thus the US Patent and the instant application sufficiently overlap it the subject matter and thus are not patentably distinct from each other.

5. Claims 43-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6566355 in view of Wong et al. (US 6083747) and D'Andrea et al. (US5378808) or Nakahata (US5610056). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The US Patent claims a method for mobilizing hematopoietic progenitor cells from bone marrow into peripheral blood comprising administering to a patient in need of chemotherapy an amount effective for mobilizing hematopoietic progenitor cells from bone marrow into peripheral blood of at least one active agent comprising a sequence of at least four contiguous amino acids of groups R.sup.1 -R.sup.8 in the sequence of general formula I.

R.sup.1 --R.sup.2 --R.sup.3 --R.sup.4 --R.sup.5 --R.sup.6 --R.sup.7 --R.sup.8 (see claim 1). The US patent specifically claims wherein the active agent is selected of angiotensinogen, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:28, SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO: 32, SEQ ID NO:33, SEQ ID NO: 34; SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, and SEQ ID NO:42 (see claim 3). Note that these are the same sequences claimed in the instant application. The difference between the US patent and the instant claims is that the US patent does not specifically disclose the augmentation of erythroid progenitor cells.

Hematopoietic stem cells are undifferentiated cells capable of self-renewal and differentiation into committed progenitor cells of the myeloid, erythroid, megakaryocytic and lymphoid blood cell lineages (see col. 1, lines 21-30 in Wong et al.). Erythropoiesis is the production of the red blood cells occurring in the bone marrow under the physiological control of erythropoietin (see col. 1, lines 16-30 of D' Andrea et al). It is generally accepted that erythropoietin is the primary humoral regulator of erythropoiesis and that it is the single factor which supports the proliferation and terminal maturation of erythroid cells from hematopoietic stem cells (see col. 1, lines 45-57 in Nakahata). Thus, a method of mobilizing hematopoietic progenitor cells from bone marrow into peripheral blood results in ertyrhopoiesis since erythropoiesis is the production of the red blood cells occurring in the bone marrow. Accordingly, the US Patent and the instant application sufficiently overlap it the subject matter and thus are not patentably distinct from each other.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.